K955164

510(k) SUMMARY FOR THE HABLEY MEDICAL TECHNOLOGY CORPORATION S.A.R.S. II™ (SEMI-AUTOMATIC-RECONSTITUTING-SYSTEM)

MAR 20 1996

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3. Date Prepared

November 8, 1995

4. Device Name

S.A.R.S. II™ (Semi-Automatic-Reconstituting-System)

Device Common or Usual Name

Drug Reconstitution System

Classification Status and Panel

These devices have not been classified by the Food and Drug Administration as of this date. However, Piston Syringes have been classified by the General and Plastic Surgery Devices Panel as Class II devices under 21 CFR 880.5860.

5. Predicate Devices

Vetter Lyo-Ject System, the Abbott ADD-Vantage System (K941545), and the UpJohn Mix-O-Vial.

6. Intended Use

Intended Use

The Habley Medical Technology Corporation S.A.R.S. II™ (Semi-Automatic-Reconstituting-System) is intended for the mixing of an approved two component drug and for delivering the mixed drug (according to the drug labeling) to a receptacle such as an IV Bag for subsequent patient administration.

Device Description

The Habley Medical Technology Corporation S.A.R.S. II™ (Semi-Automatic-Reconstituting-System) is made up of three components: 1) a syringe adapter assembly, 2) a vial adapter assembly, and 3) a syringe.

The syringe adapter assembly attaches to the piston syringe via a Luer lock connector. The syringe adapter assembly consists of a central cavity which houses an elastomeric valve. The needle cannula is situated within the elastomeric valve and is held in place by a retaining plate. A cannula carrier and coil compression springs are also contained in the syringe adapter assembly and are engaged when the three components are coupled together. When coupled the cannula passes through and is fixed to the cannula carrier. Movement of the cannula and cannula carrier against the coil compression spring causes extension into the interior and opens end of the barrel of the conventional syringe.

The piston syringe that attaches to the syringe adapter assembly is composed of a conventional piston syringe (21 CFR 880.5860). The syringe to be used with the S.A.R.S. II™ will be purchased from a manufacturer of legally marketed syringes. The S.A.R.S. II™ is compatible with any size piston syringe with a standard Luer lock fitting.

The vial adapter assembly attaches to the syringe adapter assembly via an interlocking mechanism. This consists of inwardly extending lugs positioned in the vial adapter assembly that are aligned with outer slots of a retainer ring on the syringe adapter assembly. The interlock of the two components cause an automatic alignment of the activation pin.

The vial adapter assembly includes the threaded vial adapter, safety cup, spring arms to secure the vial, needle cannula, and elastomeric seal. The spring arms activate the piercing mechanism after the components are threaded together. The safety cup size and shape is conformable to conventional drug vials. The syringe adapter assembly includes the elastomeric valves, needle cannula, and latches for attachment to vial adapter assembly or IV Bag. The needle cannula provides a stainless steel fluid pathway between the piston syringe and the vial of an approved drug component or drug.

The Habley Medical Technology Corporation S.A.R.S. II™ (Semi-Automatic-Reconstituting-System) will be commercialized in the following configurations:

- S.A.R.S. II™ including the vial and syringe adapter assemblies. This device will be packaged in a blister pack and provided sterile.

- S.A.R.S. II™ including the vial assembly and syringe adapter assemblies and a piston syringe having a volume of 5, 10, 20 or 30 ml.